DE: 4150-28

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the committee will discuss and vote on a recommendation pertaining to a proposed update to the 2020 Public Health Service (PHS) Guideline for Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection. The following question will be posed to the committee: Does the available data support exempting solid organ transplant candidates who are ≤10 years of age at the time of transplant (and who have received postnatal infectious disease testing) from the recommendation for HIV, Hepatitis B virus, and Hepatitis C virus testing during the hospital admission for transplant but prior to anastomosis of the first organ?

DATES: The meeting will take place virtually on Wednesday, December 1, 2021 from approximately 11:00 am – 3:00 pm Eastern Time (ET). Meeting times are tentative and subject to change. The confirmed times and agenda items for the meeting will be posted on the ACBTSA webpage at https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-12-01/index.html when this information becomes available. **FOR FURTHER INFORMATION CONTACT:** James Berger, Designated Federal Officer

for the ACBTSA; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330

C Street SW, Suite L600, Washington, DC, 20024. (202) 795-7608 or Email: ACBTSA@hhs.gov.

SUPPLEMENTARY INFORMATION: The ACBTSA is a discretionary Federal advisory committee. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees. On the day of the meeting, please go to https://www.hhs.gov/live/index.html to view the meeting. The public will have an opportunity to present their views to the ACBTSA by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide written public comment should review instructions at https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-12-01/index.html and respond by midnight November 26, 2021, ET. Written public comments will be accessible to the public on the ACBTSA webpage prior to the meeting.

ACBTSA functions to provide advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national survey and data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.

Dated: October 27, 2021.

James J. Berger,

Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability,

Office of Infectious Disease and HIV/AIDS Policy.

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